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Via FedEx

March 30, 2018

Lynn Muzzey
Licensing and Compliance, Bureau of Air Quality
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017

Re: 06-096 CMR 115 Air License Minor Revision
The Jackson Laboratory, Ellsworth, Maine

Dear Lynn,

Woodard & Curran is submitting this Air License Minor Revision application on behalf of The Jackson Laboratory (JAX) 21 Kingsland Crossing facility located in Ellsworth, Maine. The facility currently operates under Minor Source Air License A-1127-71-A-N issued on April 28, 2017. The license permits the operation of combustion equipment as well as an ethylene oxide (EtO) sterilization unit. The facility is currently permitted to operate a 3M Steri-Vac Sterilizer GS5X but is requesting authorization to install a 3M Steri-Vac Sterilizer GS8X unit. The new sterilizer unit will use the same EtO Abator 50AN to control emissions as the previous unit. In addition, JAX would like to modify the naming convention of the boilers and generators to reflect the as-installed nomenclature. Specifically, JAX is proposing the following the following modifications:

Table 1: Proposed Combustion Equipment Naming Convention

Equipment	Maximum Capacity [MMBtu/hr]
~~Boiler #1~~ Boiler #3	25.0
Boiler #2	25.0
~~Boiler #3~~ Boiler #1	8.0
~~Generator #1~~ Generator A	12.6
~~Generator #2~~ Generator B	12.6

The proposed changes constitute a minor revision pursuant to 06-096 CMR 115 Section 5(a)(4), as the emissions increase will not exceed 4 tons per year (TPY) for any single regulated pollutant or 8 TPY of total regulated pollutants. The information provided herein includes updated emission calculations provided in Attachment A and specifications for the new EtO sterilization unit in Attachment B. The responsible official signatory sheet is included in Attachment C.

An insignificant increase in volatile organic compounds (VOC), hazardous air pollutants (HAPs), and carbon dioxide (CO_2) will result from the increased size of the new EtO sterilization unit. The increases for these pollutants are well below the thresholds that would trigger a minor modification. Due to the insignificant emission changes, the Best Available Control Technology (BACT) Analysis and the regulatory applicability analysis associated with the initial EtO unit application remain applicable.

Should you have any questions regarding this letter or the facility's air compliance in general, please don't hesitate to reach out to me at 207-558-3684 or craymond@woodardcurran.com.

Sincerely,

WOODARD & CURRAN

Celia Raymond, P.E.
Technical Manager

Attachment A: New EtO Sterilization Unit Calculations
Attachment B: New EtO Sterilization Unit Specification Sheets
Attachment C: Responsible Official Signatory Sheet

cc: Joshua Young, The Jackson Lab
Norm Burzdel, The Jackson Lab

Attachment A: New EtO Sterilization Unit Calculations

Ethylene Oxide Sterilization Unit

Sterilizer Make: 3M
Sterilizer Model: Steri-Vac™ Sterilizer GS8X
Abator Model: EO Abator 50AN

Table 1: Potential EtO Emissions Based on Continuous Operation

EtO per Cartridge:	170	[gm/batch]
	0.37	[lb/batch]
Minimum Batch Time:	4.5	[hrs/batch]
Potential Operation:	8760	[hrs/yr]
Number of Units:	1	[-]
Potential Batches:	1947	[batches/yr]
EtO Usage Per Year:	730	[lbs/yr]
Abator Control:	99.9%	[%]
EtO Emissions:	**1**	**[lbs/yr]**

Table 2: Potential CO_2 Emissions Based on Continuous Operation

EtO Usage Per Year:	730	[lbs/yr]
EtO Destruction Efficiency:	99.9%	[%]
EtO Destroyed Per Year:	728.857	[lbs/yr]
Moles EtO Destroyed:	16.5	[lbmol]
Moles of CO_2 Produced:	33.1	[lbmol]
CO_2 Produced Per Year:	1456.4	[lbs/yr]
	0.73	[TPY]

Table 3: Emissions Increase

Pollutant	Steri-Vac™ Sterilizer GS5X Emissions [TPY]	Steri-Vac™ Sterilizer GS8X Emissions [TPY]	Net Emissions Change [TPY]
VOC	3.50E-04	3.65E-04	1.44E-05
HAP	3.50E-04	3.65E-04	1.44E-05
CO_2	6.99E-01	7.28E-01	2.87E-02

Attachment B: New EtO Sterilization Unit Specification Sheets

3M™ Steri-Vac™ Sterilizer/Aerator GS Series

3M™ Steri-Vac™ Sterilizer/Aerator GS Series is a 100% ethylene oxide sterilization system that is an effective and safe low temperature sterilization method for medical devices and other applications. The GS Series sterilizers, Models GS5 and GS8 are designed for use in health care, and Models GS5X and GS8X for use in life science, medical device, contract sterilization, R&D laboratory applications, and other research and industrial applications for terminal sterilization. The GS Series sterilizers provide control and independent monitoring with state-of-the-art, compliant mechanical design.

Specifications			Models GS5 and GS5X	Models GS8 and GS8X
Dimensions and Weight	Shipping Weight	Single Door	163 kg (359 lbs.)	387 kg (852 lbs.)
		Double Door	172 kg (379 lbs.)	400 kg (882 lbs.)
	Operational Weight	Single Door	131 kg (290 lbs.)	314 kg (692 lbs.)
		Double Door	141 kg (310 lbs.)	328 kg (722 lbs.)
	Exterior Dimensions H x W x D		70.9 × 76.2 × 95.0 cm (27.9 × 30.0 × 37.4 in.)	179.8 × 94.0 × 109.0 cm (70.8 × 37.0 × 42.9 in.)
Sterilization Chamber	Volume		136 L (4.8 ft³)	224 L (7.9 ft³)
	Dimensions H x W x D		38.0 × 43.0 × 83.0 cm (15.0 × 17.0 × 32.5 in.)	46.0 × 51.0 × 97.0 cm (18.0 × 20.0 × 38.0 in.)
	Load Basket Dimensions W x L x H	Lower Basket:	39.0 × 80.0 × 18.0 cm (15.5 × 31.5 × 7.0 in.)	34.0 × 95.0 × 20.0 cm (18.5 × 37.5 × 8.0 in.)
		Upper Basket:	39.0 × 80.0 × 18.0 cm (15.5 × 31. × 7.0 in.)	47.0 × 47.0 × 20.0 cm (18.5 × 18.5 × 8.0 in.)
Sound	Sound Levels		< 85 dBA	
Electrical Power	Voltage Range		200–240 VAC	
	Frequency		50/60 Hz	
	Phase		Single	
	Current		15 amp dedicated circuit	
	Heat Load		5500 Btu/hr	6150 Btu/hr
	Internal Circuit Breaker		7 amp	12 amp
Environmental Operating Conditions	Altitude		2500 M (maximum)	
	Operating Temperature		15–35°C	
	Humidity		20–80% relative humidity (non-condensing)	
	Room Air Exchanges		10 per hour (minimum)	
	Minimum Room Size		30 m³ (1000 ft³)	
Compressed Air Specifications	Pressure		7.0 kg/cm² (100 psig) minimum to 10.5 kg/cm² (150 psig) maximum	
	Flow Rate		2.2 liters per second at 5.3 kg/cm² (4.7 cubic feet per minute at 75 psig) per sterilizer, 100% duty cycle compressor	
	Quality		Clean air supply with a maximum allowable dirt particle size of 0.5 microns and free of oil	
	Moisture Content		Less than 10°C (50°F) dew point	
Required Service Access	Minimum distance from rear wall		10.2 cm (4 in.)	
	Minimum access on both sides and top		51 cm (20 in.)	
	Service Footprint H x W x D		70 × 76 × 89 cm (27 ½ × 30 × 35 in.)	179 × 94 × 109 cm (70 ½ × 37 × 43 in.)
Ethylene Oxide Storage Requirements	Cabinet		Approved flammable liquid storage cabinet	
	Venting		Vented to outside or to a non-recirculating, continuously operating, dedicated exhaust system	
	Size		Volume to hold two months supply	

For more information, U.S. customers contact the **3M Health Care Customer Helpline: 1 800 228 3957.**

Outside of the U.S., contact your local 3M office. See www.3M.com for office locations.

Additional site planning information is available in the 3M™ Steri-Vac™ Sterilizer/Aerator GS Series Site Planning & Installation Guide.

3M Health Care
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1-800 228 3957
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Attachment C: Responsible Official Signature Page

Section K:SIGNATORY REQUIREMENT

Each application submitted to the Department must include the following certification signed by a Responsible Official*:

"I certify under penalty of law that, based on information and belief formed after reasonable inquiry, I believe the information included in the attached document is true, complete, and accurate."

Responsible Official Signature	3/30/2018 Date
Joshua Young Responsible Official (Printed or Typed)	3/30/2018 Title

* A Responsible Official is defined by MEDEP Rule, Chapter 100 as:

A. For a corporation: a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

(1) The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars); or

(2) The delegation of authority to such representatives is approved in advance by the permitting authority;

B. For a partnership or sole proprietorship: a general partner or the proprietor, respectively;

C. For a municipality, State, Federal, or other public agency: Either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a Regional Administrator of EPA).